K011978

AUG - 9 2001

3. Summary of Safety and Effectiveness Information

Sponsor	Synthes (USA) 1690 Russell Road Paoli, PA 19301
Company Contact	Matthew M. Hull (610) 647-9700 ext. 7191
Name of the Device	Synthes LCP Proximal Tibia Plate
Device Classification	Class II, §888.3030 – Plate, Fixation, Bone, Non-spinal, Metallic
Predicate Device	- Synthes Locking Proximal Tibia Plate (K002361)
Device Description	The Synthes LCP Proximal Tibia Plates are contoured to match the anatomy of the proximal tibia with a limited contact low profile design. There are plates designed for either the right or left tibia in a variety of shaft lengths. These plates will be available in both 3.5 mm and 4.5 mm versions. The plates are available in a variety of lengths. The locking screw holes accept both cannulated locking and conical screws. Two proximal round holes accept cortex screws, cancellous screws, or cannulated screws. The distal portion of the plate has combination dynamic compression locking screw holes that allow the option of using locking screws, cortex screws, or cannulated screws.
Indications	Synthes LCP Proximal Tibia Plate is intended treatment of non-unions, malunions, and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression, and fractures with associated shaft fractures.
Materials	316L Stainless Steel

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 9 2001

Mr. Matthew M. Hull
Senior Regulatory Specialist
Synthes (USA)
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K011978
Trade/Device Name: Synthes LCP Proximal Tibia Plate
Regulation Number: 888.3030
Regulatory Class: II
Product Code: HRS
Dated: June 20, 2001
Received: June 25, 2001

Dear Mr. Hull:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General
Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Indications for Use Statement

510(k) Number (if known): K011978

Device Name: Synthes LCP Proximal Tibia Plate

Indications for Use:

Synthes LCP Proximal Tibia Plate is intended treatment of non-unions, malunions, and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression, and fractures with associated shaft fractures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K011978